GAU 1614 28

CERTIFICATE OF MAILING
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ATTORNEY FOR APPLICANT

October 5, 2000
DATE

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Attorney Docket No. P31158X1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vere Hodge, et al.

Serial No.: 08/945,249 Group Art Unit No.: 1614

Filed: 2 February 1998 Examiner: B. Travers

For: Use of (R)-Penciclovir Triphosphate for the Manufacture of a Medicament for the Treatment of Viral Diseases

TRANSMITTAL LETTER

Transmitted herewith is a Response in the above-identified application.

EXTENSION OF TIME PETITION

Applicants hereby petition for an extension of time for response from the date of the Examiner's action as needed, the fee being as follows:

( )	one month extension.....	$ 110
( )	two months extension.....	$ 390
(X)	three months extension.....	$ 890
( )	four months extension (not beyond statutory time period).....	$1390
( )	five months extension	$1890

Charge **$890.00** to Deposit Account No. 19-2570. Two copies of this form are enclosed.

Please charge any additional fees under 37 CFR 1.16 or 1.17 which may be required by this paper, or credit any overpayment, to Deposit Account No. 19-2570. Also, should the Patent and Trademark Office determine that the fee calculated in the above extension petition is not deemed sufficient to have this response considered as being timely filed, this constitutes a petition for extension of time for the minimum period to effect timely filing, and the Commissioner is authorized to debit any necessary fee to said deposit account.

Respectfully submitted,

Dara L. Dinner
Attorney for Applicants
Registration No. 33,680

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#26 10/19/00

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Vere Hodge et al.	5 October 2000
Serial No.:	08/945,249	Group Art Unit No.: 1614
Filed:	2 February 1998	Examiner: R. Travers
For:	Use of (R)-Penciclovir Triphosphate For the Manufacture of A Medicament For the Treatment of Viral Diseases	

Assistant Commissioner of Patents
Washington, D.C. 20231

RESPONSE

Sir:

In response to the Examiner's Action mailed 11 April 2000, having a shortened statutory period of three(3) months, please enter the following Remarks and Amendments into the record. Also enclosed herewith is a petition for a three (3) month extension of the shortened statutory period set by the Examiner and authorization to charge the required fee to the indicated deposit account.

Remarks

Claims 1, 3 to 14, and 16 to 20 are in the application. Claims 3, and 5 to 14 are held withdrawn from consideration as being drawn to non-elected subject matter.

Rejection under 35 USC §103

1, 4, and 16 to 20 are rejected under 35 USC §103 as being unpatentable over Kenig et al. or Boyd et al., all of record. Applicants respectfully traverse this rejection.

Applicants reiterate that both the Kenig et al., and the Boyd et al. references do not disclose penciclovir triphosphate, nor do they disclose the (R)-isomer of this compound. Both the Kenig et al. and the Boyd et al. patent application as are directed to different uses of Penciclovir. There is no teaching that phosphate esters of

penciclovir could exist as enantiomers. There is no teaching of the specific bioprecurser phosphate esters claimed herein in claims 4, and 16 to 20.

It could not have been predicted that the (R) PCV-TP enantiomer would be a more active inhibitor of HBV DNA polymerases and HIV-1 reverse transcriptase than the (S)-enantiomer of PCV.

The Examiner has indicated that "Absent an illustration of unexpected benefits residing in one, or another, isomer these uses are obvious to the skilled artisan".

It is unclear exactly why Applicants should need to submit the data on page 4 in declaration form as the specification contains a declaration. However, in order to advance prosecution on the merits, Applicants will submit under separate cover a declaration from a skilled artisan who has reviewed the three abstracts as cited on page 4, lines 14-22 of this application.

The three abstracts in question for support of unexpected activity are: Session 43, p 182, H13 (San Francisco, CA, USA, Sept. 17-20, 1995), ("Zoulim *et al*"); Abstracts of the 35th Interscience Conference on Antimicrobial Agents and Chemotherapy, Session 43, p191, H66 (San Francisco, CA, USA, Sept. 17-20, 1995), ("Shaw *et al*"); and Programme and Abstracts of the Eighth International Conference on Antiviral Research, A304, 146 (Santa Fe, NM, USA, April 23-28, 1995), ("Schinazi *et al*").

The contents of the three abstracts may be summarized as follows:
Zoulim *et al* shows that (R)–penciclovir triphosphate ("(R)-PCV-TP") is markedly more potent than (S)-penciclovir triphosphate ("(S)-PCV-TP") against HIV-1 reverse transcriptase; Shaw *et al* shows that (R)-PCV-TP is more efficient than (S)-PCV-TP in inhibiting duck hepatitis B virus reverse transcription; and Schinazi *et al* shows that (R)-PCV-TP is more potent than (S)-PCV-TP as an inhibitor of HBV DNA polymerases.

The declaration will state that the data presented in these three abstracts shows that (R)-PCV-TP is more potent than (S)-PCV-TP for inhibiting HIV and HBV replication.

If this is not sufficient, or the Examiner has a different type of declaration in mind please advise the undersigned as soon as possible.

The Examiner also states that "If Applicants attest to published data, that such data was done at their direction and guidance; these averments will support averments of un-obviousness". It should be noted that one of the publications is by Schinazi et al. and Dr. Schinazi is an inventor of the present application. Therefore, he has attested to such data and has knowledge of this data by the filing of this application and any

additional declarations by Dr. Schinazi are completely unnecessary to substantiate the Examiner's position.

The Kenig et al., and Boyd et al. references do not provide a teaching, nor direction to direct the skilled artisan to synthesize specific phosphate esters of PCV, let alone (R) and (S) PCV-TP, in enantiomerically pure form. Kenig and Boyd et al. also do not provide a teaching nor direction for the specific use of these claimed phosphate esters of PCV (claims 1, 4 and 16 to 20) in the treatment of use with HIV-1 or HBV infections (page 4, lines 1 to 5 and Claim 1).

In light these remarks, Applicants respectfully request reconsideration and withdrawal of the rejection to Claims 1, 3 to 14 and 16 to 20 under 35 USC §103.

Conclusion

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

Dara L. Dinner
Attorney for Applicants
Registration No. 33,680

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